REMARKS

Claims 13-29 are pending herein. By this Amendment, non-elected Claims 1-12 are canceled without prejudice or disclaimer; Claim 13 is amended; and new Claims 21-29 are added. Support for the claim amendments and new claims is found in the specification at, *inter alia*, page 4, lines 1-16. No new matter is added by this Amendment.

I. RESTRICTION REQUIREMENT

Applicants respectfully maintain that the restriction requirement is improper for the reasons set forth in the Election In Response to Restriction Requirement filed July 14, 2003. The Examiner asserts that restriction is proper because stanniocalcin is known and is therefore not a "special technical feature". However, Claims 1-12 recite a pharmaceutical composition that contains stanniocalcin as an effective ingredient for treating obesity. The composition is not taught or suggested by any cited reference and it is a special technical feature common to both the composition and method claims. Further, the definition of a special technical feature is determined in light of the specification and does not require any preliminary determination of patentability. Nevertheless, to advance prosecution, non-elected Claims 1-12 are canceled without prejudice or disclaimer.

II. FORMAL MATTERS

EP 0 750 626 B1 and JP 9-511140, which were listed on Form PTO-1449 filed with the Information Disclosure Statement on March 16, 2001, were not considered because copies of these references could not be located by the Examiner. The Notice of Acceptance dated November 22, 2002 states that the U.S. Patent and Trademark Office received copies of the references cited in the International Search Report from the

International Bureau. Applicants note that both EP 0 750 626 B1 and JP 9-511140 are equivalent to international PCT publication WO 95/24411, which has been considered by the Examiner. Thus, copies of these references are unnecessary.

The Abstract was objected to because it is not a single paragraph. The Abstract is deleted and a new Abstract in paragraph form is submitted. Reconsideration and withdrawal of the objection are respectfully requested.

The Examiner requested a new title that is indicative of the claimed invention. A new Title is provided which recites Method for Treating Obesity and for Inhibiting Adipocyte Activity. Reconsideration and withdrawal of the objection are respectfully requested.

As suggested by the Examiner, the specification is amended to recite that the application is a U.S. national stage application of PCT/JP99/05080 filed September 17, 1999, which claims priority of Japanese patent application 10-263004 filed September 17, 1998.

III. REJECTION UNDER 35 U.S.C. 112, FIRST PARAGRAPH

Claims 13-20 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. This rejection is respectfully traversed.

The Examiner asserts that prevention or treatment of obesity is a multi-factorial process that includes physiological and psychological components. The Examiner also asserts that the specification provides no *in vivo* data for the prevention or treatment of obesity and has not demonstrated that the *in vitro* method is a predictive model for using stanniocalcin to prevent or treat obesity.

In vivo data is not necessary in order to satisfy the enablement requirement. According to MPEP 2164.02, an *in vitro* model constitutes a working example if that example "correlates" with a claimed method invention. The issue of correlation is

dependent upon the state of the art. If a particular model is recognized as correlating to a specific condition, then it should be accepted as correlating unless the examiner has evidence that the specific model does not correlate. Applicants respectfully note that a rigorous or invariable exact correlation is not required. See MPEP 2164.02 citing *Cross v. Iizuka*, 224 USPQ 739, 747 (Fed. Cir. 1985) (therefore a rigorous correlation is not necessary where the disclosure of pharmacological activity is reasonable based upon the probative evidence).

Although obesity may have several components, including psychological components, the Examiner has not provided any reason or evidence as to why the specific model given in the specification does not correlate to the treatment of obesity. Moreover, even if a person were to become obese from a psychological factor, fat that is excessively accumulated in adipocytes would still be a major cause of obesity. Further, one of the references cited by the Examiner (Science, *Strategies and Molecular Targets for Obesity Treatment*, pp. 1383-1387) explicitly discusses pharmacological intervention for treating obesity based on biochemical pathways and molecular targets. In fact, the Science article discusses different classes of anti-obesity drugs, including those that inhibit fat absorption and those that decrease triglyceride synthesis. See page 1383 and Table 1. The references cited by the Examiner also discuss the prevention of obesity.

Applicants respectfully submit that one of ordinary skill in the art would appreciate that the determination of adipogenesis inhibitory activity using mouse preadipocytic cell strain 3T3/L1 as in Example 2 on pages 12-13 of the specification provides a reasonable correlation between: (1) the inhibition of adipocyte activity as measured by triglyceride accumulation and (2) the treatment of obesity. According to Lea-Currie et al., *Dehydroepiandrosterone Reduces Proliferation and Differentiation of 3T3-L1 Preadipocytes*, Biochem. & Biophys. Research Comm. 497-504 (1998), dehydroepiandrosterone (DHEA) reduces proliferation and differentiation of pre-

adipocytic cell strain 3T3-L1. See Discussion beginning on page 500. In particular, FIG. 4 shows that the amount of stained lipid decreased as the level of DHEA increased. Further, Lea-Currie et al. states:

> Numerous reports (6-13) have demonstrated that DHEA treatment (100-400 mg/kg body weight) of mice and rats reduces body weight gain and carcass lipid. Furthermore, our group has reported that DHEAS treatment ... of growing male Sprague-Dawley rats reduced fat pad weights, percentage body fat, adipocyte number and serum triglyceride levels without affecting food or water intake (14).

See page 497, right hand column, emphasis added. A copy of Lea-Currie et al. is included with a Supplemental Information Disclosure Statement filed concurrently herewith. Lea-Currie et al. supports the correlation between inhibition of adipogenesis in 3T3-L1 cells and the treatment of obesity. Example 1 of the specification also supports the treatment of obesity by using another pre-adipocytic cell strain, MC3T3-G2/PA6. Accordingly, Claims 13-20 are enabled and satisfy the requirements of 35 U.S.C. 112, first paragraph. Reconsideration and withdrawal of the rejection are respectfully requested.

IV. REJECTION UNDER 35 U.S.C. 112 SECOND PARAGRAPH

Claims 13-20 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

Claim 13 is amended to recite a method for treating obesity which comprises administering to humans a pharmaceutically effective amount of stanniocalcin in the form of a pharmaceutical composition. New Claim 21 recites a method for treating obesity which comprises administering to animals a pharmaceutically effective amount of stanniocalcin in the form of a pharmaceutical composition. Thus, Claim 13 does not contain a narrower limitation within a broader limitation. The scope of pending Claims

13-20 would be reasonably ascertainable to one of ordinary skill in the art when read in light of the specification. Thus, the requirements of 35 U.S.C. 112, second paragraph, are satisfied. Reconsideration and withdrawal of the rejection are respectfully requested.

IV. CONCLUSION

In light of the foregoing remarks, this application is in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application.

Enclosed is a check in the amount of $258.00 for the additional independent claim fee. Any shortages in fees should be charged to, or any overpayment in fees should be credited to, Deposit Account No. 501032 (Docket #FJIN-107).

Respectfully submitted,

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February 26, 2004

Enclosure: Check for $258.00

CERTIFICATE OF MAILING
I hereby certify that this correspondence dated 2/26/04 is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 2/26/04.

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